

EXAMPLE 13 (cont'd)Amount per 1 ml

Disodium EDTA, USP

1.00 mg

Citric acid monohydrate, USP

12.19 mg

Sodium citrate dihydrate,  
USP

12.37 mg

Hydrochloric acid, ACS

To adjust pH to 4.0

If needed

Sodium hydroxide, ACS

To adjust pH to 4.0

Water for injection, USP

q.s. to 1 ml

EXAMPLE 14Amount per 1 mlCalcitonin<sup>8</sup>

1428.0 I.U.

 $\Delta$ -aminolevulinic acid

5.0 mg

Benzalkonium chloride

solution, N.F., 50%

0.20 mg

Disodium EDTA, USP

1.00 mg

Citric acid monohydrate, USP

12.19 mg

Sodium citrate dihydrate, USP

12.37 mg

Hydrochloric acid, ACS

To adjust pH to 4.0

If needed

Sodium hydroxide, ACS

To adjust pH to 4.0

Water for injection, USP

q.s. to 1 ml

The gelatin used in the above formulations is a standard hydrolyzed animal gelatin prepared for pharmaceutical use and routinely used as a diluent for peptides.

<sup>1</sup> Synthetic salmon calcitonin having a potency of 4,000 MRC (Medical Research Council) units.

Examples 17, 18 and 19.

The following compositions were prepared according to the method described in Examples 1 to 9.

Table 7

	Example No.		
	17	18	19
Elcatonin (μg) (6500 I.U./mg potency)	7380	3690	3690
Ammonium Glycyrrhizinate (g)	0.5	0.5	1
Citric Acid (mg)	37	37	37
Sodium citrate dihydrate (mg)	463	463	463
Methyl p-hydroxybenzoate (mg)	130	130	130
Propyl p-hydroxybenzoate (mg)	20	20	20
Distilled water	q.s. to 100 ml		
1N NaOH	q.s. to pH 6		

Examples 20-25

Table 8

	Example No.					
	20	21	22	23	24	25
Elcatonin (μg) (6500 I.U./mg potency)	7380	3690	7380	3690	7380	3690
Ammonium glycyrrhizinate (g)	0.5	0.5	1	1	2	2
Citric acid (mg)	37	37	37	37	37	37
Sodium citrate dihydrate (mg)	463	463	463	463	463	463
Methyl p-hydroxybenzoate (mg)	130	130	130	130	130	130
Propyl p-hydroxybenzoate (mg)	20	20	20	20	20	20
Sodium chloride (mg)	600	600	600	600	600	600
Polysorbate 80 (mg)	5	5	5	5	5	5
Distilled water	q.s. to 100 ml					
1N NaOH	q.s. to pH 6					

The formulations of Examples 20 to 25 were prepared by mixing together the ammonium glycyrrhizinate, citric acid, sodium citrate dihydrate, methyl p-hydroxybenzoate, propyl p-hydroxybenzoate, sodium chloride, polysorbate 80, distilled water and sodium hydroxide in a water bath regulated at a temperature of about 60°C. The resulting solution was allowed to cool to room temperature and the elcatonin was then added.